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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,695	03/27/1998	PATRICIA A. BILLING-MEDEL	6066.US.PI	5913

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/06/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/049,695

Applicant(s)

Billing-Medel et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10, 13, 14, 16, and 19-39 is/are pending in the application.
- 4a) Of the above, claim(s) 7-10, 13, 14, 16, and 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: **attachment**

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 11, 2003 has been entered.

2. Claims 28, 29 and 31 have been amended. Claims 34-39 have been added. Claims 7-10, 13, 14, 16 and 19-39 are pending. Claims 7-10, 13, 14, 16 and 19-27 remain withdrawn from consideration. Claims 28-39 are under consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 28-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28, 31, 34 and 37 recite "degenerate coding sequences thereof" after the recitation of SEQ ID NO representing polynucleotide sequences. Without recitation of a polypeptide sequence to which the degenerate coding sequences are directed, the metes and bonds of this limitation cannot be construed.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 28-33 are drawn to polynucleotide sequences comprising SEQ ID NO:1, 23 and 24. Claims 34-39 are drawn to polynucleotides consisting essentially of SEQ ID NO:2 and SEQ ID NO:25. Section 2111.03 of the M.P.E.P states

"A consisting essentially of claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir.1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963).

The specification provides no mention and therefore no guidance in defining the limitation "consisting essentially of". Accordingly, the claims will be read as "comprising". The specification teaches that SEQ ID NO:1, 2, 23, 24 and 25 are EST sequences, and thus represent partial cDNAs. The specification discloses that SEQ ID NO:5 is the consensus sequence deduced from the individual partial sequences. On page 52, lines 18-26 the specification states that the first forward frame of SEQ ID NO:5 was found to be an open reading frame encoding SEQ ID NO:16. The specification does not disclose whether or not a given EST sequence crosses an intron/exon junction, therefore polynucleotides which comprise the EST sequences can be genomic sequences having introns and regulatory regions which have not been described, in addition to cDNA sequences which have not been described. Each of SEQ ID NO: 1, 2, 23, 24

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and 25 represent a separate genus of polynucleotides which minimally comprises the EST sequences. Further, claims 28, 31, 34 and 37 recite "degenerate coding sequences thereof" without a limitation regarding a polypeptide which is being encoded. When given the broadest reasonable interpretation, the coding sequences can be apprised from any frame, both forward and backward, of the given EST sequences. It is reasonable to conclude that proteins translated from polynucleotides which start at different frames within said polynucleotides would result in a completely different amino acid sequence. The degenerate coding sequences thereof for each EST sequence thus comprise an additional set of polynucleotide sequences which encompass polynucleotides which are not related by function to the instant SEQ ID NO:5 which has been predicted to encode SEQ ID NO:16. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by the nucleotide sequence falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Here the specification discloses only a single common structural feature shared by members of the claimed genus, i.e. SEQ ID NO: 1, 2, 23, 24 and 25, and the genus is highly variant because they encompass polynucleotides which differ in functional attributes from the claimed EST sequences. Because the genus is highly variant the disclosure of the partial sequences of SEQ ID NO:1, 2, 23, 24 and 25 fail to describe the claimed genus. One of skill in the art would conclude that applicant was not in possession of the claimed genus for each of SEQ ID NO: 1, 2, 23, 24 and 25.

8. The rejection of claims 28-33 under 35 U.S.C. 102(e) as being anticipated by Lal et al (US 5,856,139) is maintained for reasons of record. The rejection of new claims 34-39 is made for the same reasons of record. Claim 28 is drawn in part to the polynucleotide of SEQ ID NO:24. Claim 31 is drawn in part to the DNA molecule of SEQ ID NO:24. Claims 29 and 32 embody the

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polynucleotides and DNAs of claims 28 and 31, respectively, wherein said molecule is produced by recombinant techniques. Claims 30 and 33 embody the polynucleotides and DNAs of claims 28 and 31, respectively, wherein said molecule is produced by synthetic techniques. Claim 34 is drawn to the polynucleotides of SEQ ID NO:2 and SEQ ID NO:25. Claim 37 is drawn to a DNA molecule of SEQ ID NO:2 and SEQ ID NO:25. Claims 36 and 39 embody the polynucleotides and DNAs of claims 34 and 37, respectively, wherein said molecule is produced by recombinant techniques. Claims 35 and 38 embody the polynucleotides and DNAs of claims 34 and 37, respectively, wherein said molecule is produced by synthetic techniques.

Lal et al disclose the polynucleotide of Sequence 2 which comprises SEQ ID NO:2, 24 and 25 as evidenced by the attached alignments. Lal et al disclose the polynucleotides as DNA and RNA (column 3, lines 13-21) and obtaining said polynucleotides by synthetic and recombinant techniques (column 8, lines 36-44, column 10, lines 30-38 and column 11, lines 32-41).

9. Applicant argues that inclusion of the limitation “consisting essentially of” obviate the rejection under 102(e) as being anticipated by Lal et al. This is not persuasive, for the reasons set forth above regarding the lack of teaching in the specification for defining “consisting essentially of” versus “comprising”. Applicant has provided no argument regarding the anticipation by Lal et al of claims 28-33 drawn to polynucleotides comprising SEQ ID NO: 1, 23 and 24.

10. All other rejections and objections as set forth in a previous Office action are withdrawn..

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "Karen A. Canella", followed by a horizontal line.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 28, 2003